

# Decision Memo for Bariatric Surgery for the Treatment of Morbid Obesity (CAG-00250R)

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## Decision Summary

The Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is adequate to conclude that open and laparoscopic Roux-en-Y gastric bypass (RYGBP), laparoscopic adjustable gastric banding (LAGB), and open and laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS), are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI)  $\geq 35$ , have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity.

CMS has determined that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

A list of approved facilities and their approval dates will be listed and maintained on the CMS Coverage Web site at [www.cms.hhs.gov/center/coverage.asp](http://www.cms.hhs.gov/center/coverage.asp), and will be published in the Federal Register.

The evidence is not adequate to conclude that the following bariatric surgery procedures are reasonable and necessary; therefore, the following are non-covered for all Medicare beneficiaries:

1. open vertical banded gastroplasty;
2. laparoscopic vertical banded gastroplasty;
3. open sleeve gastrectomy;
4. laparoscopic sleeve gastrectomy; and
5. open adjustable gastric banding.

The two non-coverage determinations in the National Coverage Determination Manual (NCDM) remain unchanged - Gastric Balloon (NCDM Section 100.11) and Intestinal Bypass (NCDM Section 100.8).

Modification of the current policy on obesity, found in section 40.5 of the NCDM, will include a reference to the covered surgical procedures and will merge the obesity policy with the final bariatric surgery policy. The modified obesity policy will read as follows (emphasis added to the new language within the policy):

Obesity may be caused by medical conditions such as hypothyroidism, Cushing's disease, and hypothalamic lesions or can aggravate a number of cardiac and respiratory diseases as well as diabetes and hypertension. ***Certain designated surgical services for the treatment of obesity are covered for Medicare beneficiaries who have a BMI  $\geq$  35, have at least one co-morbidity related to obesity and have been previously unsuccessful with the medical treatment of obesity.***

Treatments for obesity alone remain non-covered.

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## Decision Memo

TO: Administrative File: CAG-00250R  
Bariatric Surgery in Medicare Beneficiaries - Reconsideration

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SUBJECT: Coverage Decision Memorandum for Bariatric Surgery for Treatment of Co-morbidities Associated with Morbid Obesity

DATE: February 21, 2006

## I. Decision

The Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is adequate to conclude that open and laparoscopic Roux-en-Y gastric bypass (RYGBP), laparoscopic adjustable gastric banding (LAGB), and open and laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS), are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI)  $\geq 35$ , have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity.

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Treatments for obesity alone remain non-covered.

## II. Background

### Epidemiology

Obesity is a growing epidemic in the United States; over 60% of the population is classified as overweight or obese.<sup>1</sup> Overweight and obese persons have an increased risk of a number of diseases compared to those with normal weight and waist circumference. Some of the most important and common co-morbidities include hypertension; dyslipidemia; type 2 diabetes; coronary heart disease; stroke; gallbladder disease; osteoarthritis; sleep apnea; respiratory problems; and endometrial, breast, prostate, and colon cancers. Because of the relative lack of success of most weight loss programs, persons with co-morbid conditions related to obesity have turned to bariatric surgery at an exponentially increasing rate. The treatment of co-morbid conditions related to obesity by bariatric surgery is the focus of this decision memorandum.

The National Heart, Lung, and Blood Institute (NHLBI) has classified overweight people into groups based on Body Mass Index (BMI is the body weight in kilograms divided by the body height in meters squared):

Overweight = BMI 25-29.9  
Class I obesity = BMI 30.0-34.9  
Class II obesity = BMI 35.0-39.9  
Class III (Extreme) Obesity = BMI  $\geq 40.0$

By these definitions, approximately 27% of the US population is obese and an additional 34% is overweight. Obesity is more common in women and a BMI in the overweight range is more common in men. Obesity is especially common in African Americans, Native Americans, Native Hawaiians, and some Hispanic populations.<sup>2</sup> Data for the extent of obesity in the Medicare population indicate that in 1999-2000, 33% of men and 39% of women aged 65-74 were obese as were 20% and 25% respectively over the age of 74.<sup>3</sup>

### **Surgical Treatment**

Extremely obese persons often do not benefit from the non-surgical treatments for weight loss and weight maintenance.<sup>4</sup> The Massachusetts Technology Assessment (TA) reported that weight loss in bariatric surgery studies was of a magnitude greater than weight loss in pharmaceutical or diet studies. It cited a weight loss of 20-40 kg at one or two years in surgical studies versus 2-5 kg in pharmaceutical studies.<sup>5</sup>

Using data from the National In-patient Survey (NIS), Pope reported that the rate of performance of bariatric surgery procedures increased from 2.7 to 6.3 per 100,000 adults from 1990 to 1997. During the same time period, gastric bypass surgery increased from 54% to 84% of all bariatric surgery in the US.<sup>6</sup> As of 2003, the predicted number of bariatric surgery procedures was over 100,000 per annum.<sup>7</sup>

Several modifications of bariatric surgery have developed over the last several years. Two major types of surgery are now being employed. One type diverts food from the stomach to a lower part of the digestive tract where the normal mixing of digestive fluids and adsorption of nutrients cannot occur – a malabsorptive procedure. The other type restricts the size of the stomach and decreases intake – a restrictive procedure. Other surgeries combine both types of procedures. Initially, bariatric surgery was developed as an open procedure, but in recent years, successful attempts have been made to convert some of the procedures to laparoscopic procedures, while new ones have been developed solely as laparoscopic procedures. The following are descriptions of bariatric surgery procedures:

#### **Roux-en-Y Gastric Bypass (RYGBP) (Open/Lap)**

RYGBP achieves weight loss through both gastric restriction and malabsorption. Reduction of the stomach to a small gastric pouch (30 cc) results in feelings of satiety following even small meals. This small pouch is connected to a segment of the jejunum, bypassing the duodenum and very proximal small intestine, thereby reducing absorption. The RYGBP procedure has been performed regularly since the early 1980s and was first performed laparoscopically in the early 1990s. RYGBP is one of the most common types of weight loss procedures in current use, with approximately 50,000 cases performed in 2001.

#### **Biliopancreatic Diversion (BPD) with and without Duodenal Switch (DS) (Open/Lap)**

BPD/DS, like RYGBP, combines both restrictive and malabsorptive mechanisms. The stomach is partially resected, but the remaining capacity is generous compared to that achieved with the RYGBP. As such, patients eat relatively normal-sized meals and do not need to restrict intake radically, since the most proximal areas of the small intestine (i.e., the duodenum and jejunum) are bypassed, and substantial malabsorption occurs. Although this procedure is less commonly performed than either banding procedures or RYGBP, the approach is strongly favored by some bariatric surgeons because this procedure appears to yield higher Excess Weight Loss (EWL). The partial biliopancreatic diversion with duodenal switch is a variant of the BPD procedure. Recently, a number of centers in the United States and Canada have begun to perform this procedure, which involves resection of the greater curvature of the stomach, preservation of the pyloric sphincter, and transection of the duodenum above the ampulla of Vater with a duodeno-ileal anastomosis and a lower ileo-ileal anastomosis.

#### Laparoscopic Adjustable Gastric Banding (LAGB) (Lap)

Gastric banding achieves weight loss by gastric restriction, not malabsorption. A band creating a gastric pouch with a capacity of approximately 15 to 30 cc's encircles the uppermost portion of the stomach. The band is an inflatable doughnut-shaped balloon, the diameter of which can be adjusted in the clinic by adding or removing saline via a port that is positioned beneath the skin. The bands used today are adjustable, allowing the size of the gastric outlet to be modified as needed, depending on the rate of a patient's weight loss. Today, essentially all of the banding procedures are performed laparoscopically. The open version of adjustable gastric banding (AGB) is not performed at present.

#### Sleeve Gastrectomy (Open/Lap)

Sleeve gastrectomy is a 70%-80% greater curvature gastrectomy (sleeve resection of the stomach) with continuity of the gastric lesser curve being maintained while simultaneously reducing stomach volume. It may be the first step in a two-stage procedure when performing RYGBP.

#### Vertical Gastric Banding (VBG) (Lap)

VBG uses mechanical restriction to cause weight loss, a similar mechanism to that used in LAGB, with no malabsorption component. However, the upper part of the stomach is stapled, creating a narrow gastric inlet or pouch that remains connected with the remainder of the stomach. In addition, a non-adjustable band is placed around this new inlet in an attempt to prevent future enlargement of the stoma (opening). As a result, patients experience a sense of fullness after eating small meals. Weight loss from this procedure results entirely from eating less. VBG was one of the more common surgical procedures for weight loss in the late 1980s and early 1990s but has been largely supplanted by LAGB since 1995. Now its role in the treatment of patients with severe obesity is limited. The open version of VBG is essentially no longer performed.

### **III. History of Medicare Coverage**

#### *Current Coverage Policies*

#### **NCD Manual Section 40.5 Obesity**

Obesity may be caused by medical conditions such as hypothyroidism, Cushing's disease, and hypothalamic lesions, or can aggravate a number of cardiac and respiratory diseases as well as diabetes and hypertension. Services in connection with the treatment of obesity are covered when such services are an integral and necessary part of a course of treatment for one of these medical conditions. However, program payment may not be made for treatment of obesity unrelated to such a medical condition since treatment in this context has not been determined to be reasonable and necessary.

#### **NCD Manual Section 100.1 *Gastric Bypass Surgery for Obesity***

Gastric bypass surgery for extreme obesity is covered under the program if (1) it is medically appropriate for the individual to have such surgery; and (2) the surgery is to correct an illness which caused the obesity or was aggravated by the obesity.

#### **NCD Manual Section 100.8 *Intestinal Bypass***

The safety of intestinal bypass surgery for treatment of obesity has not been demonstrated. Severe adverse reactions such as steatorrhea, electrolyte depletion, liver failure, arthralgia, hypoplasia of bone marrow, and avitaminosis have sometimes occurred as a result of this procedure. It does not meet the reasonable and necessary provisions of §1862(a)(1) of the Act and is not a covered Medicare procedure. (NOTE: This procedure is not under consideration in this NCD.)

#### **NCD Manual Section 100.11 *Gastric Balloon***

The gastric balloon is a medical device developed for use as a temporary adjunct to diet and behavior modification to reduce the weight of patients who fail to lose weight with those measures alone. It is inserted into the stomach to reduce the capacity of the stomach and to affect early satiety. The use of the gastric balloon is not covered under Medicare, since the long term safety and efficacy of the device in the treatment of obesity has not been established. (NOTE: This procedure is not under consideration in this NCD.)

#### ***Request for Reconsideration***

On May 23, 2005, CMS opened a national coverage determination (NCD) at the request of the American Society for Bariatric Surgery, the American Obesity Association, Ethicon Endo-Surgery Inc. (a Johnson & Johnson company), INAMED Corp., U.S. Surgical, a division of Tyco Healthcare Group LP, and Transneuronix Corp. The requestors asked that Medicare cover the following bariatric surgery procedures:

- a. open Roux-en-Y gastric bypass;
- b. laparoscopic Roux-en-Y gastric bypass;
- c. open adjustable gastric banding;
- d. laparoscopic adjustable gastric banding;
- e. open biliopancreatic diversion with duodenal switch;
- f. laparoscopic biliopancreatic diversion with duodenal switch;
- g. open vertical banded gastroplasty;
- h. laparoscopic vertical banded gastroplasty;

- i. open sleeve gastrectomy; and
- j. laparoscopic sleeve gastrectomy.

Surgical treatment for co-morbid conditions related to obesity, as addressed in sections 40.5 and 100.1 of the NCD Manual, will be reviewed in this NCD. Sections 100.8 and 100.11 were not part of the request, and, as we are unaware of any new evidence of benefit from these procedures or the use of these procedures currently, we will not review these sections in this decision memorandum.

#### *Benefit Category Determination*

Under §1861(q) of the Social Security Act (the Act) bariatric surgery is a physician service, and as such qualifies as a benefit. Evaluation and management services of patients with obesity for whom bariatric surgical procedures are contemplated may also be considered to be a benefit as physicians' services.

Bariatric surgery procedures may be considered to be a benefit as inpatient hospital services under §1861(b) of the Act and certain services and supplies may be considered to be a benefit to hospital outpatients under §1861(s)(2)(B) of the Act, "incident to" a physician's service.

Bariatric surgery, as considered in this decision memorandum, is used for the treatment of co-morbidities and medical complications related to obesity and, therefore, is not considered cosmetic surgery.

#### **IV. Timeline of Recent Activities**

From August 1, 2004, to November 11, 2004, CAG prepared an evidence review and summary of evidence for the Medicare Coverage Advisory Committee (MCAC).

On November 4, 2004, the Evidence Review and Summary of Evidence was presented at the MCAC on Bariatric Surgery.



On May 23, 2005, CMS accepted a formal request for reconsideration of the existing policy on gastric bypass and initiated a review.

On June 24, 2005, initial comments were posted to the tracking sheet, which is available electronically at: [http://www.cms.hhs.gov/mcd/viewpubliccomments.asp?nca\\_id=160](http://www.cms.hhs.gov/mcd/viewpubliccomments.asp?nca_id=160).

On November 23, 2005, CMS posted the proposed decision memorandum and invited public comment.

## **V. FDA Status**

Surgical procedures are not subject to FDA approval. However, LapBands™ are utilized in some bariatric surgery and the date and content of FDA approval for this device can be found at <http://www.fda.gov/cdrh/mda/docs/p000008.pdf>.

## **VI. General Methodological Principles**

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve net health outcomes for patients. An improved net health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

A detailed account of the methodological principles of study design that the agency utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix A. In general, features of clinical studies that improve quality and decrease bias include the selection of a clinically relevant cohort, the consistent use of a single good reference standard, and the blinding of readers of the index test, and reference test results.

Public comment sometimes cites the published clinical evidence and gives CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum

## **VII. Evidence**

### *Introduction*

In order to appraise the benefits of bariatric surgery for co-morbid conditions related to obesity in comparison with non-surgical medical management, CMS chose the following outcomes:

- sustained weight loss;
- short- and long-term mortality;
- complications of surgery (also using length of stay as a marker); and
- effect on co-morbidities.

The acceptable studies concentrated on these outcomes and our review of the evidence demonstrated these outcomes to be most important when evaluating the effectiveness and impact of bariatric surgery procedures. We also looked for these outcomes in both patients with co-morbidities and without co-morbidities.

We assessed the health benefits of bariatric surgery via a review of the literature and through input from the Medicare Coverage Advisory that met on November 4, 2004.

### *Discussion of Evidence Reviewed*

#### **1. Questions**

Is the evidence sufficient to conclude that the following bariatric surgery procedures will improve net health outcomes for Medicare patients:

- a. open Roux-en-Y gastric bypass;
- b. laparoscopic Roux-en-Y gastric bypass;
- c. open adjustable gastric banding;
- d. laparoscopic adjustable gastric banding;
- e. open biliopancreatic diversion with duodenal switch;
- f. laparoscopic biliopancreatic diversion with duodenal switch;
- g. open vertical banded gastroplasty;
- h. laparoscopic vertical banded gastroplasty;
- i. open sleeve gastrectomy; and
- j. laparoscopic sleeve gastrectomy.

The evidence reviewed included external technology assessments, a CMS internal technology assessment of new or reconsidered evidence, as well as professional society position statements and expert opinion.

## 2. External Technology Assessments

### **“Clinical Guidelines on The Identification, Evaluation, And Treatment of Overweight and Obesity in Adults: The Evidence Report.” National Heart, Lung, and Blood Institute (NHLBI). 1998.**

The NHLBI report examined articles from January 1980 through September 1997 regarding gastric bypass, gastroplasty with diet, VBG, horizontal-banded gastroplasty (HBG), BPD/DS, and RYGBP. According to the report, co-morbid conditions improved after VBG and RYGBP. Complications following surgery, however, were frequent and substantial and included readmission, depression, staple line failure, dilated pouch, and dehydration/malnutrition. If less invasive weight loss treatments fail in patients at high risk for obesity-related morbidity or mortality, NHLBI recommended bariatric surgery as an option for carefully selected patients with a BMI > 40 or > 35 with co-morbidities. There was no discussion of the effects of bariatric surgery of those 65 years of age or older.

### **“Pharmacological and Surgical Treatment of Obesity.” Southern California Evidence-Based Practice Center. RAND Corporation. July 2004: for Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services.**

Rand reviewed articles dating from 1966 to 2003 regarding gastric banding, VBG and other gastroplasty, jejunoileal bypass, RYGBP, and BPD/DS. The report found that surgery controls obesity-related co-morbid conditions more effectively than non-surgical treatments. No clear differences in mortality or complications exist between different surgical procedures. Overall mortality for bariatric surgery remained between 1 and 2%. No recommendations were made beyond future research priorities. There was limited discussion on bariatric surgery and this assessment did not address bariatric surgery in people 65 years or older.

### **“Newer Techniques in Bariatric Surgery for Morbid Obesity.” The Technology Evaluation Center (TEC) of the Blue Cross and Blue Shield Association. September 2003.**

The Blue Cross Blue Shield TEC examined articles from January 1985 through August 2003 regarding open and laparoscopic gastric banding, BPD/DS, and long-limb gastric bypass. Due to insufficient data, the committee remained unable to confidently evaluate the safety and net health benefit of any of the bariatric surgeries except RYGBP. The TA calculated mortality associated with RYGBP as being between 0.5 and 0.6%. No recommendations were made beyond the acceptance of Roux-en Y as the sole procedure meeting BCBS TEC criteria for coverage. The mean age for study participants did not exceed 50.

**“Executive Report.” Commonwealth of Massachusetts Betsy Lehman Center for Patient Safety and Medical Error Reduction. Expert Panel on Weight Loss Surgery. August 4, 2004.**

The Massachusetts expert panel reviewed articles published between January 1980 and February 2004 regarding RYGBP, VBG, gastric banding, and BPD/DS. The report maintained that laparoscopic and open RYGBP improve or resolve many co-morbid conditions, but benefits of LAGB remain unclear. RYGBP risks were reported to be substantial and include pulmonary embolism, intestinal leak, wound infection, staple line failure and long-term nutritional deficiencies. Laparoscopic techniques had a steeper learning curve than other equivalent open procedures. LAGB risks included band- and port-related problems, GERD, and esophagitis. The LAGB revision rate may have been as high as 10%. LAGB mortality (< 0.5%) was found to be lower than mortality for RYGBP or BPD/DS. The expert panel provided extensive and specific recommendations regarding bariatric surgeons and bariatric surgery programs. There was no discussion of bariatric surgery in the elderly.

**“Diagnosis and Treatment of Obesity in the Elderly.” University of Pittsburgh. December 18, 2003: for Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services.**

This TA reviewed articles published between January 1980 and February 2003 regarding gastric bypass, LAGB, VBG and DS. According to this assessment, current data were insufficient to evaluate safety or efficacy of bariatric surgery in the elderly. In young obese patients, surgery was shown to improve diabetes, hypertension, dyslipidemia and quality of life (QOL), but higher age increased the perioperative risk of bariatric surgery. The report stated that surgical data were poor and adverse events had the capacity to be very serious, including death. No recommendations were made beyond future research suggestions to analyze the effects of surgery in the elderly.

**“Bariatric Surgery for Obesity.” ECRI. September 2004: for Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services.**

ECRI reviewed articles regarding bariatric surgery in persons aged  $\geq 18$  years, published in 1994 or later, having either a randomized controlled trial (RCT) or a before/after comparison with morbid obesity and having sample size of  $\geq 10$ . Concentration was on outcome of QOL and co-morbidity reduction. ECRI found strong evidence that bariatric surgery reduced short-term mortality, labeling it in the range of 0.1 – 1.5%, while data on other outcomes was rated as weak to moderate. This assessment did a separate evaluation of evidence for bariatric surgery in obesity in adolescents (less than 21 years old). This was the only age-related assessment of evidence.

**“Laparoscopic Bariatric Surgery for Morbid Obesity.” ECRI. May 2005: for the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services.**

ECRI reviewed articles regarding a comparison of laparoscopic to open bariatric surgery published through January 2005, including studies having an RCT or meta-analysis. The TA concluded that there was not enough evidence to answer the question of outcome differences between open and laparoscopic for the modalities studied. The evidence was not evaluated by age.

### **3. Internal Technology Assessment**

#### **Literature Search**

CMS performed a search of the literature using the following terms: Bariatric OR Obesity AND Surgery AND Elderly OR Older. The limitations used were human, English, publication date from 04/04/03 to 09/01/05. The database searched was MEDLINE.

#### **Scientific Articles**

Each person on a team of four graded all 213 papers located by our search as either unacceptable or acceptable. Fifty-two papers referenced the elderly and 43 of those papers were published earlier than April 2003. Of all 213 papers, 27 were considered acceptable. Only data from acceptable papers were utilized in our Summary of Evidence. Of special note was that many of the studies reported to date had not had population samples representative of the general severely overweight population with respect to race, ethnicity, cultural or socioeconomic background, gender or age. Also of note was the paucity of randomized control trials (RCTs), non-randomized control trials (NRCTs), and good quality data for the population over age 65.

#### **Outcomes**

##### *Sustained Weight Loss*

Five of 27 acceptable articles contained data on sustained weight loss and one of 27 articles had data on sustained weight loss in persons over the age of 65. Of the seven TAs, none had sustained weight loss data on persons over age 65 and five of seven had data on sustained weight loss. We did not find data comparing sustained weight loss in persons having bariatric surgery and at least one pre-op co-morbidity with those having bariatric surgery and no pre-operative co-morbidities.

The Swedish Obese Subjects (SOS) study, a case-control study with respect to outcomes from bariatric surgery,<sup>8</sup> reported statistically significant long-term weight loss after different types of bariatric surgery (banding and gastric bypass) as compared to controls (non-surgical management). The study matched subjects at baseline on 18 variables, including gender, age, height, and weight. At eight years of follow-up, among 251 surgically treated patients, the average weight loss was 20 kg (or 16 percent of body weight) as compared to no change in the control group of 232 medically treated patients. Weight loss in the operated group ranged from 4.4-35kg. The SOS study, the only carefully-controlled trial with long-term results, also demonstrated that there was approximately 8-9 kg more sustained weight loss in gastric bypass as compared to VBG. Their results provided strong evidence of the superiority of surgical treatment for the patients that were enrolled (37-57 year olds with an average BMI of about 41kg/m<sup>2</sup>).

The NHLBI TA reported that bariatric surgery (gastric restriction [vertical gastric banding] or gastric bypass [Roux-en Y]) could result in substantial weight loss, and therefore is an available weight loss option for well-informed and motivated patients with a BMI  $\geq 40$  or  $\geq 35$  with co-morbid conditions and acceptable operative risks. They also added that RYGBP produced greater long-term weight loss than gastric partitioning alone or VBG and was substantially safer than jejunoileal bypass. The Massachusetts TA reported that open and laparoscopic RYGBP produced short-term weight loss and improvements in co-morbid medical conditions. Dolan reported that BPD with or without DS was effective in producing weight loss. LAGB produced variable short-term weight loss and improvements in obesity-related co-morbidities and had higher average mortality rates than RYGBP or malabsorptive procedures. In a case-control study by Dolan et al., it was determined that weight loss was higher in BPD/DS than in LAGB, 64% excess weight loss (EWL) versus 48%EWL at 24 months.<sup>9</sup> In a study by Shen, LAGB was compared to RYGBP and it was pointed out that in LAGB, if patients had more than 6 visits postoperatively, they had 8% more EWL (50% vs. 42%), whereas there was no difference in the RYGBP group.<sup>10</sup> Chau, in a study of LAGB, reported that after adjusting for demographics, older patients and patients with pre-existing diabetes mellitus or COPD had greater odds of above average %EWL after bariatric surgery, whereas being female, having a higher BMI, and having hypertension were risk factors for a lower %EWL result.<sup>11</sup> Suter, in a prospective randomized study comparing LAGB to the Swedish Adjustable Gastric Band (SAGB), reported that evaluation of short and midterm results of these two modalities showed an equivalent %EWL.<sup>12</sup>

The one acceptable paper that we found with sustained weight loss in persons close to age 65 was authored by Sugerman (2004). He reported on a cohort of 80 patients over age 60 with an average age of 63 years. His paper reported that, at 5 years after bypass surgery, there was an average of 27% weight loss, and 50% EWL.<sup>13</sup> Finally, in the Gonzalez study of bypass surgery for obesity in persons over age 50, weight loss plateaued at 18 months with EWL averaging 68%, similar to that in younger age groups.<sup>14</sup>

### *Short-term mortality*

In our CMS overall review, eight of 27 acceptable papers and four TAs reported data on short-term mortality results, two of which pertained partially to persons over 65. We were unable to locate any data comparing short-term mortality in persons having bariatric surgery and at least one preoperative co-morbidity, with those having bariatric surgery and no preoperative co-morbidities. The Buchwald article reported the rates of short-term mortality to be 0.1% for purely restrictive procedures, 0.5 % for gastric bypass, and 1.1% for BPD/DS.<sup>15</sup> Anthone et al. stated that they had a short-term mortality rate for BPD/DS of 1.4% in 701 consecutive patients having this procedure.<sup>16</sup> A recent paper by Hess et al. reported a 0.57% mortality rate in 1,400 cases of BPD/DS performed by his group since 1988 with overall follow-up of 91% at 10 years.<sup>17</sup> Flum reported a short-term mortality rate in Medicaid bariatric surgery (gastric bypass) patients of 1.9% and that 81% of the short-term mortality cases were associated with surgeon inexperience. Inexperienced bariatric surgeons, defined in this study as bariatric surgeons who had performed fewer than 20 operations, performed 19% of all surgical cases in that study.<sup>18</sup> Data from that paper yielded an approximately 6.0% short-term mortality rate in the hands of inexperienced surgeons, while the rate for experienced bariatric surgeons was about 0.5%. In another paper analyzing complete Medicare claims data from 1997 to 2002, Flum reported that the overall short-term mortality rate for all surgeons was 4.8% in persons over age 65, as compared to 1.7% for those under age 65, as well as a median of 3.4% short-term (30-day) mortality in the age group 65-74 years. Flum also found a reduction in all-cause mortality directly associated with surgeon experience. Of particular interest was that surgeons in the upper quartile of volume of bariatric surgical procedures performed had a 1.1% mortality rate at 90 days in persons over the age of 65 as compared to 1.8 % below the age of 65 not a significant difference.<sup>19</sup> Data regarding hospital and surgeon volume was reported in two papers that supported the premise that in general, higher volume resulted in fewer deaths and complications.<sup>20,21</sup> Livingston reported a rate of 3.2% in persons over 65 as compared to 1% for those under 65 without adjustment for surgeon experience.<sup>22</sup> In Herron's review, short-term mortality relating to gastric banding and gastric bypass was in the range of 0.0-1.0%, while in BPD/DS, it was higher at 0.5%-2.5%.<sup>23</sup> In the Pope study of the National In-hospital Survey (NIS), in-hospital mortality for all bariatric surgery was reported to be 0.37% from 1990 to 1997. In the Massachusetts TA, LAGB had a short-term mortality rate of < 0.5%.<sup>5</sup> The overall VBG range of short-term mortality was 0-1.4%<sup>15,24</sup> and for all of bariatric surgery, short-term mortality ranged from 0.1% to 2.0%.<sup>1,15,23,19</sup>

In two cohort studies by Fernandez, risk factors for peri-operative death in open or laparoscopic gastric bypass were postoperative leak, pulmonary embolus, higher pre-operative weight, and hypertension. Other risk factors for mortality were age, male gender, having diabetes, and having had a specific surgical procedure with RYGBP having a 2.7% short-term mortality rate, open RYGBP a 1.5% short-term mortality rate and LRYGBP a 0.5% rate. There were no deaths in persons older than 60 (number of cases over age 60 not shown in paper) despite the fact that being a higher age was predictive of a higher chance of mortality.<sup>25,26</sup> Livingston found that male gender is a predictor of mortality for patients undergoing gastric bypass surgery.<sup>27</sup>

### *Longevity*

With respect to longevity, four of 27 of our acceptable articles had data on longevity and two of 27 had longevity data on persons over the age of 65. Of the seven TAs we reviewed, none had any data on longevity. We were unable to locate any data comparing longevity in persons having bariatric surgery and at least one pre-operative co-morbidity, with those having bariatric surgery and no pre-operative co-morbidities.

There was some evidence that bariatric surgery patients had prolonged longevity and less Years of Life Lost (YLL). Black males aged 30, with a BMI of 40, had 8YLL as compared to 5YLL for white males aged 30 with the same BMI. White females aged 30, with BMI of 40 had roughly the same YLL as white males (4-5). These differences almost disappeared for persons aged 60 and above with a BMI of 40, with black females actually having negative years of life lost at higher ages.<sup>28</sup> Flum reported an increase in longevity in those post-bariatric surgery Medicaid patients given that they survived to year one after the surgery.<sup>18</sup>

### *Co-morbidities*

Nine of 27 of our acceptable articles had data on co-morbidities; however, none had co-morbidity data on persons over the age of 65. Of the seven TAs we reviewed, none had co-morbidity data on persons over age 65 and four of seven had data on co-morbidities in the general population.

Regarding the prevalence of co-morbidities in the population eligible for bariatric surgery, Pope demonstrated that the percentage of persons that had obesity surgery and had at least one major pre-operative co-morbidity was estimated to be 20.8% in 1990 and 31.4% in 1997. Yet in Gonzalez' cohort study, for persons 50 years old or older, 47 of 52 (90%) had co-morbidities such as: degenerative joint disease (60%), diabetes and gastroesophageal reflux disease (GERD) (40%), and hypertension (56%). Approximately 90% of each type improved post-operatively with the exception of hypertension, where 56% improved. In a study by Residori, 57% of patients had at least one metabolic complication, with 30% having diabetes, 38% dyslipidemia, and 38% hypertension.<sup>29</sup> Approximately one-third of the diabetes cases and one-half of the dyslipidemia and hypertension cases were previously undiagnosed. Dindo calculated, after adjustment for BMI and age, that the occurrence of dyslipidemia was higher in Caucasians than Hispanics or African Americans, while hypertension rates were about the same.<sup>30</sup>

In the Swedish Obesity Study (SOS), ten-year follow-up of 1,006 post-bariatric surgery patients aged 37 to 57 years showed that the two-year incidence rates of diabetes, hypertension, and low high density lipoprotein (HDL) were statistically significantly higher in the control group (diabetes 16% vs. 0.5%, hypertension 23% vs. 6.0%, and elevated HDLs 16% vs. 5.0%). From the SOS, Sjostrom<sup>8</sup> reported that the post-op prevalence of hypertension, after 8 years follow-up, showed no difference between VBG cases and controls, while there was a statistically significant lowering of hypertension in the group that had GBP as compared to the control group. One important study, the Adelaide Study (Dixon-1988), showed that medical co-morbidities either improved (47%) or resolved (43%) in all but 4 cases (9% of patients had unsatisfactory weight loss). They reported that 60 percent of the patients who initially had any obesity-related co-morbidity were free of medication for those co-morbidities 3 years after surgery.<sup>2</sup> Buchwald reported that for all types of bariatric surgery, diabetes completely resolved in 77% of cases, and improved or resolved in 86%; hypertension completely resolved in 62% and improved or resolved in 78%; hyperlipidemia improved in 70%; and obstructive sleep apnea (OSA) was resolved in 85%.<sup>15</sup> In Dolan's case-control study the resolution of co-morbidities was similar across groups having BPD/DS as compared to those having LAGB, ranging from 66% in hypertension to 100% of OSA.

### *Complications*



In our CMS review, six of 27 acceptable papers and four of seven TAs reported data on complications in patients, while two of 27 acceptable papers and no TAs reported data on persons over 65 years. We were unable to locate any data comparing complication rates in persons who had bariatric surgery and at least one pre-operative co-morbidity, with those having bariatric surgery and no pre-operative co-morbidities.

In a study by Shikora, involving a series of 750 consecutive patients undergoing LRYGBP at a high-volume academic center, the complication rate was reduced by more than 50% when comparing the first 100 cases against the next 650 in the program, regardless of performing-surgeon experience.<sup>31</sup>

The Massachusetts TA reported that laparoscopic adjustable silicone gastric banding (LAGB) had a lower complication rate than the other bariatric surgery procedures. The Dolan study showed that Lap BPD had a markedly higher rate of complication (56%) as compared to 6.3% in LAGB. Heron's review underscored the difference in rates of complications from RYGBP and BPD/DS versus VBG. For example, bypass procedures had lower re-operation rates and LAGB had lower wound infection rates. In that study, the LAGB complications were somewhat lower than those in either RYGBP, BPD/DS, or VBG and a known complication of LRYGBP was conversion from LRYGBP to the open procedure during surgery. A study by Felix showed that 3% of laparoscopic procedures were converted to open, while other studies showed a range of 1.6% re-operations in RYGBP, 11.3% in VBG, and 7.7 to 10% in LAGB.<sup>32</sup> In the converted group, risk factors for conversion were higher age, higher weight, and male gender.

In other types of complications, Fernandez identified risk factors for having a leak as male gender, having diabetes, and open or laparoscopic RYGBP.<sup>25</sup> In general, the NHLBI reported that wound infections ranged from 2.3% in laparoscopic cases to 11.4% in open cases. In the Livingston study on procedure and in-hospital complication rates using NHIS data, risk factors for complications were higher age and being male. In that study, the most frequent complication was pneumonia (at 2.6%), while the short-term mortality rate was 0.4%. Over the 1990 to 1997 period, Pope found significant decreases of in-hospital re-operations for bleeding, abscess, or dehiscence (2.2% to 1.4%); respiratory complications (7.4% to 5.9%); and a trend toward decreased in-hospital complications. The RAND TA reported reduced occurrence of wound and incisional hernia complications in patients treated laparoscopically, compared to open procedures. Malnutrition occurred in 2.5% in VBG to 16.9% in RYGBP and 5.8% for all bariatric surgery.<sup>1,2</sup> Notable in another Livingston study was that male gender was a predictor of morbidity for patients undergoing gastric bypass surgery.<sup>33</sup>

#### **4. Medicare Coverage Advisory Committee (MCAC)**

At the MCAC meeting on bariatric surgery, held on November 4, 2004, a number of questions were presented to the Committee for consideration. Details of that meeting, including an evidence summary, the voting questions and a transcript are available at <http://www.cms.hhs.gov/mcd/viewmcac.asp?where=index&mid=26>. A summary of the MCAC recommendations is presented below.

- With regard to bariatric surgery in persons with one or more co-morbidities, the MCAC indicated that the evidence presented addressed the effectiveness of bariatric surgery in the treatment of obesity in patients with one or more co-morbidities compared to non-surgical medical management. The Committee members were confident regarding the validity of the scientific data presented on weight loss and felt confident that bariatric surgery would very likely result in sustained weight loss as compared to non-surgical management.

- With respect to the outcomes of short-term mortality, long-term mortality, and co-morbidities, the Committee was moderately confident in the validity of the scientific data presented, and believed that bariatric surgery would positively affect these outcomes when compared to non-surgical management.

- Regarding the different types of bariatric surgery in obese persons with one or more co-morbidities, the Committee had a generally moderate to high confidence in the ability of all the modalities considered (RYGBP, BPD/DS, and Banding) to yield a net health benefit. RYGBP drew the most support.

- With regard to bariatric surgery in persons with no co-morbidities, data was insufficient to answer any of the questions presented.

- Lastly, based on the scientific evidence presented, the MCAC believed, with moderate confidence, that even though the evidence in the over-65 population was sparse, the results of bariatric surgery in obese patients under the age of 65 with one or more co-morbidities could be generalized to the older Medicare population.

## **5. Guidelines**

We have reviewed the certification requirements for both the ACS and the American Society for Bariatric Surgery and will review both of those here. The complete programs are outlined in Appendices 5A and 5B.

The ACS Bariatric Surgery Network has two levels of facility with differing requirements. The differences are outlined in the table below. The Level 1 requirements are extensive and include requirements addressing multispecialty services, anesthesiology services, critical care services, comprehensive endoscopy services, comprehensive minimally invasive surgery, comprehensive imaging services, full service operating rooms, recovery room, emergency room, dialysis facilities for acute renal failure, trained staff, mandatory outcomes reporting, quality improvement program, use of best evidence guidelines, clinical pathways, and algorithms, education and training of bariatric surgeons, patient selection process, patient education, counseling, and informed consent, discharge and follow-up plan, postoperative rehabilitation and long term follow-up, surgeon credentialing criteria to include standards for newly trained surgeons and established surgeons who want to perform bariatric surgery, surgeon recredentialing, outcomes data collection, on-site review, and an appeal process.

<b>Differences between Level 1 and Level 2 of ACS Guidelines</b>		
<b>Characteristic</b>	<b>Level 1</b>	<b>Level 2</b>
Hospital type	Tertiary	Acute
Facility Volume	At least 125 annually	At least 25 annually
Surgeon Volume	At least 50 per surgeon	1 <sup>st</sup> time – 25 lap or 10 open Recertification. -At least 50 in previous 2 years
Surgeon Number	At least two on staff	At least one
Board Certification by ABS	Yes	Yes
Age (years)	Under 70	Under 60
BMI	No limit	Less than 50

Differences between Level 1 and Level 2 of ACS Guidelines		
Characteristic	Level 1	Level 2

We have also reviewed the guidelines for the ASBS Centers of Excellence (see Appendix 1B). Their criteria include an institutional commitment at the highest levels of the applicant medical staff and the institution's administration; credentialing guidelines for bariatric surgery; an expectation that the applicant institution will perform at least 125 bariatric surgical cases per year; an expectation that each applicant surgeon will have performed at least 125 total bariatric cases lifetime with at least 50 cases performed in the preceding 12 month period; a designated physician Medical Director for bariatric surgery who participates in the relevant decision-making administrative meetings of the institution; a full complement on staff of the various consultative services required for the care of bariatric surgical patients, a full line of equipment and instruments for the care of bariatric surgical patients including furniture, wheel chairs, operating room tables, beds, radiologic capabilities, surgical instruments and other facilities suitable for morbidly obese patients; utilization of clinical pathways and orders that facilitate the standardization of perioperative care for the relevant procedure; utilization of a designated nurse or physician extenders who are dedicated to serving bariatric surgical patients and who are involved in continuing education in the care of bariatric patients; an organized and supervised support groups for all patients who have undergone bariatric surgery at the institution; a program dedicated to a goal of long-term patient follow-up of at least 75% for bariatric procedures at five years with a monitoring and tracking system for outcomes; and an agreement to provide annual outcome summaries to SRC in a manner consistent with Health Insurance Portability and Accountability Act (HIPAA) regulations.

## 6. Public Comments

During the initial comment period, for the proposed decision memorandum, CMS received 169 public comments; 78% were positive comments in support of providing coverage for bariatric surgery for co-morbid conditions related to obesity and 22% were negative and opposed to Medicare coverage of bariatric surgery. Those comments can be found on our website. We included our responses to these comments in our proposed decision memorandum, which is also available on our website.

In our proposed decision memorandum, CMS requested general public comments as well as specific comments on the following questions:

1. What is the adequacy of the evidence to conclude that open and laparoscopic Roux-en-Y gastric bypass (RYGBP) and laparoscopic adjustable gastric banding (LAGB) are reasonable and necessary for Medicare beneficiaries under the age of 65?
2. Should CMS consider expansion of bariatric surgery coverage for this population under the Coverage with Evidence Development (CED) option?
3. CMS has suggested some basic facility standards for those institutions performing bariatric surgery. What is the potential to establish more definitive bariatric surgery criteria for facilities and surgeons, including volume criteria, and what are the appropriate entities to apply these standards and their level of competence? The decision memorandum refers to the certifying programs of the American College of Surgeons (ACS) and the American Society for Bariatric Surgery (ASBS).
4. What is the adequacy of the evidence to conclude that open and laparoscopic RYGBP and LAGB are not reasonable and necessary for Medicare beneficiaries over the age of 65? Is there potential to cover this population under CED?

CMS received 537 public comments in response to our proposed decision memorandum (see Appendix 2 for Graph of Commenter Types).

- 327 commenters were patients, of which 277 had experienced bariatric surgery
- 46 commenters were involved in the business or care of bariatric surgery patients but were not physicians
- 66 commenters were physicians
- 5 commenters were professional organizations
- 78 commenters were public citizens who were not related to patients
- 15 commenters were public citizens who were related to patients

There were no comments opposed to our proposed decision, regarding the effectiveness and safety of RYGBP and LAGB

## **A. Comments with Evidence**

### Medicare beneficiaries age > 65

Bariatric surgeons who commented generally had a favorable opinion of the proposed decision. They basically recognized Flum's work and agreed that there was an increased risk when performing bariatric surgery on patients over age 65. However, they were in general agreement that the benefits of surgery in reducing the co-morbidities outweighed the surgical risks. Many of the surgeons sent journal article references supporting their positions. We were able to utilize acceptable data from eight of the 30 articles referred to CMS by commenters (Appendix 4). A few surgeons related their experiences over an extended period of surgical practice.

Five comments were received from professional societies. Most commented on the growing problem of morbid obesity in the older population and wrote that CMS should reconsider covering bariatric surgery in the over 65 population.

Flum commented that his review demonstrated that surgeons with high volumes had outcomes as good or better in the 65 and older population as in the under-65 population.

Based on these comments and a re-evaluation of the data on surgical risk, we are revising our decision to provide coverage of identical procedures in the older population and younger population.

#### Biliopancreatic diversion with duodenal switch (BPD/DS)

Seven bariatric surgeons commented that the final National Coverage Determination should include coverage for biliopancreatic diversion with duodenal switch because the procedure results in superior effectiveness for maximal weight loss.

We also received references on BPD/DS from commenters. One paper with 1,400 cases predominantly performed by one surgeon<sup>17</sup> reported a short-term mortality rate of less than 1%. This low mortality rate is supported by Flum,<sup>18,19</sup> who reported that experienced surgeons have a much lower short-term mortality rate.

The American College of Surgeons submitted a comment and stated that CMS should “give duodenal switch a chance” because the rate of not achieving a 50% EWL, considered failure, is only 35% in persons less than 65 years old.

We believe the new data submitted is persuasive and will expand our proposed decision to include this procedure.

#### VBG - open and laparoscopic

Three commenters spoke to VBG. Two supported laparoscopic VBG referring to one paper, and one commenter reported having abandoned laparoscopic VBG for BPD/DS. We repeated our review of the literature and again find that the data available is insufficient to determine that these procedures improve health outcomes in any age beneficiary.

#### Sleeve Gastrectomy

Sixteen commenters referred to sleeve gastrectomy, all with positive comments. Twelve were professionals and 4 were patients. One commenter referred us to papers on this procedure and we reviewed them. This data as well as other data in the literature are sparse or of poor quality. The level of evidence has resulted in the marked decrease in use of this one-time popular bariatric procedure. We again find that the data is insufficient to determine any health benefit.

### Medical therapy prior to surgery

One bariatric surgery group wrote that it favored bariatric surgery for those over age 65 and standardized facility criteria, but believed that a medical treatment weight loss trial for 6 to 12 months was not necessary. They commented that the decision of when to perform surgery was best left to the surgeon and the patient.

Generally, a common comment introduced pertained to the subjective nature of the medical treatment requirement prior to surgery. Some stated that there were no data to support such a requirement and others stated that the requirement only prolonged the time to needed surgery.

The standard of care for any surgical procedure is that medical management options are exhaustively considered and exercised by both patient and physician prior to surgery. This standard applies to the treatment of co-morbid conditions related to obesity. We will not impose a specific time period, but expect all surgeons to be part of a comprehensive program for the treatment of co-morbid conditions related to obesity and to have applied principles of good medical care prior to surgery.

### Facility/surgeon criteria

The American Society for Bariatric Surgery, one of the NCD requesters, cited several studies supporting surgeon volume requirements. It noted that a Center of Excellence (COE) should require 125 bariatric surgery cases annually and each surgeon should perform at least 50 bariatric surgery procedures per year. In addition, it supported surgery for patients over age 65 only in centers where a high volume of bariatric surgery is performed.

Additionally, commenters referred us to papers by Nguyen and Corcouras, both reporting that high volume in centers and in surgeons had a beneficial effect on complication rates. <sup>20,21</sup>

The American College of Surgeons supported facility criteria and surgeon volume requirements.

The ACS upper age limit for bariatric surgery recipients is 70. One of its requirements for certification for a level 1 facility is performance of at least 125 bariatric surgery operations per year, including at least two surgeons who do at least 50 bariatric surgery procedures per year. For recertification, surgeons must have performed at least 50 bariatric surgery procedures in the past 2 years. The American College of Surgeons also agreed that the procedure should be provided at bariatric surgery Centers of Excellence as designated by a professional oversight entity and that surgeon volume should be considered.

Thirty-three commenters addressed the question of support for certain potential certifying entities. Of these, 24 came from professionals, mostly practicing MDs, who were unanimous in supporting the ACS and/or the ASBS as approved certifying entities. The other 9 comments were from entities or persons in the business of bariatric surgery and all supported either ACS and/or ASBS.

## **B. Comments without Evidence**

Public comments that are submitted without evidence are generally not as persuasive as those comments submitted with substantive and evidentiary information. Most of these respondents were supportive of bariatric surgery. Other comments were offered on a variety of issues.

### Coverage with evidence development

We received 22 comments, all positive, from physicians and professional societies to the effect that continuing data collection should be encouraged. However, we did not receive significant comments that encouraged the conditioning of coverage on a data collection system. Thus, we will not expand coverage using the CED concept.

## **VIII. CMS Analysis**

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act §1862(l)(6)(A). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” §1862(a)(1)(A) of the Act.



Medical treatment for obesity includes dietary manipulation, behavior modification and medication. These therapies have been tried individually and in combination, but with only limited long-term success. However, based on the lower risk-benefit ratio for medical treatment, we believe it should be routinely attempted and shown to be unsuccessful before considering a patient for bariatric surgery. There are no consistent standards in the literature regarding length of a medical treatment trial and, therefore, we are unable to specify a specific time interval. A number of trials and guidelines recommend 6 to 12 months and we believe that to be reasonable.

In our review we found, in the general population, that post-surgical sustained weight loss may be an attainable goal with combination or malabsorptive procedures showing greater weight loss than restrictive procedures, which, in turn, demonstrate significantly more weight loss than no surgery. The NCD requestors recommended that bariatric surgery procedures be covered for beneficiaries with a BMI  $\geq 35$  with at least one co-morbidity or with a BMI  $\geq 40$  without any co-morbidity. In general, for outcomes of short- and long-term mortality, improvement in co-morbidities, sustained weight loss and complications of surgery, we found there is little or no data enabling comparisons of persons who had at least one pre-operative co-morbidity with those who had none. We did find supporting evidence that sustained and sufficient weight loss may improve or resolve co-morbid conditions. Buchwald et al., in their JAMA meta-analysis, reported that overall, bariatric surgery resulted in a 61.2% (58.1-64.4) EWL. They also reported that, as a result of that EWL, co-morbidities such as diabetes, hyperlipidemia, obstructive sleep apnea and hypertension improved or resolved in a majority of patients.<sup>15</sup> The data are consistent with the conclusion that health benefits of surgery are limited to those persons with one or more co-morbidities related to obesity. Therefore, we believe that bariatric surgery should be reserved for that group.

With respect to Medicare beneficiaries under the age of 65, we found that there was sufficient evidence to support open and laparoscopic RYGBP and LAGB as reasonable and necessary for selected patients in this younger population as well as new evidence supporting BPD/DS. For these modalities, sustained weight loss was well documented (ranging from an approximate mean of 60% EWL in BPD/DS to 50% EWL in RYGBP to approximately 30-50% in LAGB) and short- and long-term mortality were low (<2%).<sup>1,4,5,15,16,17,8</sup> Thus, we will expand our proposed coverage decision to include BPD/DS. However, we found that data supporting open vertical banded gastroplasty, laparoscopic vertical banded gastroplasty, open sleeve gastrectomy, laparoscopic sleeve gastrectomy, and open adjustable gastric banding are generally sparse and not adequate to draw conclusions in this population. We had limited comments on both vertical banded gastroplasty and sleeve gastrectomy supporting their use. We repeated our evidence review of these procedures and again find little evidence of health benefit. Thus, we will continue our proposed non-coverage of these procedures.

With respect to the Medicare population age 65 and older, we have reconsidered our proposed decision. In that memorandum, we expressed concern that the results of trial data in patients under 65 years of age could not be generalized to the older population due to the significantly higher surgical risk. As discussed above, new data and analyses provided during the comment period demonstrate that surgeons in the highest quartile of bariatric surgery procedure volumes had similar rates of early mortality in both age groups (1.8 % 90-day mortality in patients less than 65 years and 1.1 % mortality in patients greater than 65 years). Excluding high volume surgeon experience as a factor, overall mortality rates in the 65 and older population were 2.8 times higher at 30 days, 3 times higher at 90 days and 2.85 times higher at one year, when compared to the population under age 65.<sup>19</sup> Livingston, like Flum, has demonstrated the increased mortality in the older population undergoing bariatric surgery while Flum demonstrated, as already mentioned, the marked variability in outcomes based on surgical experience.<sup>19,22</sup> This reanalysis of the data on surgical volume, at both the facility and surgeon levels, identify it as a significant factor in safety for bariatric surgery. Thus, with these new data, we are modifying our proposed decision to now include the population age 65 years and older, as long as the procedures are performed in facilities that are most likely to achieve the better outcomes reported by Flum.

In our proposed decision, we identified several criteria we believe to be essential for optimizing outcomes for bariatric surgery. We initially proposed that the facility must ensure that only competent surgeons are credentialed to perform these procedures and included board certification, training and experience that meet national standards and training and experience in managing morbidly obese patient prior to, during and following surgery. We still believe these standards are crucial. As discussed above, the American College of Surgeons and the American Society for Bariatric Surgery have developed their own criteria for facilities performing this surgery. They, along with numerous other commenters, strongly support CMS in restricting Medicare coverage of these procedures to hospitals with specific expertise, equipment and staffing. In addition to surgeon qualifications, the professional societies and the commenters listed other facility criteria crucial to good outcomes. A key criterion mentioned by both organizations and numerous commenters was an adequate volume of procedures both by the facility and individual surgeons. The volume mentioned most often was 125 cases annually for each facility and 50 cases annually and 125 cases total for each surgeon within that facility. Based on our review and these comments, we agree with the addition of these specific volume criteria to our standards.

Neither our re-evaluation of the evidence nor the public comments suggested additional changes in our proposed standards. Thus, we believe that bariatric surgery for Medicare beneficiaries should be performed in facilities that have met the following facility standards:

1. Institutions will have a credentialing program that ensures that surgeons performing bariatric surgery shall have:
  - a. appropriate board certification;
  - b. performed and continue to perform at least 50 bariatric surgeries per year, with at least 125 bariatric surgery cases in a particular surgeon's past at initial certification; and
  - c. training and clinical expertise in managing and treating morbidly obese patients prior to the decision to undertake surgery and have experience in managing post-surgery patients for at least one year after surgery.
2. The institution's medical staff committee will ensure that physicians who do not meet the annual volume requirement are no longer credentialed to perform the procedures.
3. Institutions will have performed and continue to perform at least 125 bariatric surgery procedures per year for certification.
4. Institutions will ensure that individuals who provide services and/or supervise services in the bariatric surgery program are qualified to provide or supervise such services.
5. Institutions will have an integrated program for the care of the morbidly obese patients that provides:
  - a. ancillary services such as specialized nursing care, dietary instruction, counseling, support groups, exercise training, and psychological assistance, as needed; and
  - b. a multidisciplinary bariatric surgery team with written descriptions of the responsibilities of each member of the team. The team must be composed of individuals with the appropriate qualifications, training and experience in the relevant areas of bariatric surgery, rehabilitation, critical care anesthesia, and nutrition counseling for the morbidly obese and post-bariatric surgery patients.
6. Institutions will have established and implemented written policies to address and document adverse events that occur during the management of a bariatric surgery patient.
7. Institutions will have staff and readily available consultants in cardiology, pulmonology, rehabilitation and mental health who have prior experience with bariatric surgery patients.
8. Institutions will have a written informed consent process that informs each patient of:
  - a. the evaluation process;
  - b. the surgical procedure;
  - c. alternative treatments;
  - d. national-, center- and provider-specific rates for potential surgical risks, hospital lengths of stay, 30-day mortality and other relevant outcome measures;
  - e. risk factors that could affect the success of the surgery; and
  - f. the patient's right to refuse the intervention.
9. Institutions will have:

- a. sufficient operating room tables, equipment, instruments and supplies specifically designed or appropriate for bariatric surgery;
- b. a recovery room capable of providing critical care to obese patients;
- c. an intensive care unit with similar capabilities;
- d. equipment with manufacturer's specifications, such as hospital beds, commodes, chairs, wheelchairs, etc., that accommodate the morbidly obese; and
- e. radiology and other diagnostic equipment capable of handling morbidly obese patients.

We also received numerous comments on the need to follow patient outcomes on an ongoing basis. Though we now believe that the evidence is sufficient to determine that the approved procedures are reasonable and necessary in the older population, this remains a newer field of surgery with the potential for adverse outcomes. The consensus of experts is that facilities and surgeons involved in these procedures should be routinely following their patients for outcomes and adverse events. We agree with the need for additional evidence and encourage clinical trials that focus both on the procedures that provide the highest benefit with the lowest risk as well as identifying those patients who benefit most from this surgery.

CMS has reviewed the ASBS and ACS standards for certifying facilities for bariatric surgery and find that their standards are consistent with and/or exceed CMS standards listed above. We believe that the processes outlined in the ASBS program are such that only facilities with the greatest likelihood of successful outcomes will be certified. For the ACS program, we believe that Level 1 certification meets or exceeds the standards outlined above. We do not believe that ACS Level 2 certification meets those standards and CMS will not cover bariatric surgery procedures furnished in institutions that only meet the Level 2 certification. For both programs, ACS and ASBS, we believe that procedures are also in place to ensure that facilities and surgeons who fall below the minimum standards will no longer be certified as a Medicare approved bariatric surgery center.

Comments that we received from physicians and other professionals supported the ACS and the ASBS with respect to their ability to conduct certification/recertification and provide adequate assurance that the minimum standards are met. Our review of ACS and ASBS standards supports this view. Therefore, we believe that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery as a Center of Excellence (program standards and requirements in effect on February 15, 2006). Any facilities certified under altered standards would not be eligible for payment for bariatric surgery performed on Medicare beneficiaries. Any other entity that develops certification standards and desires approval as a certifying agency may provide evidence of their ability to ensure our standards are met and apply for a reconsideration of this NCD.

We will notify the public of those approved bariatric surgery facilities by posting a list on our website at [www.cms.hhs.gov/center/coverage.asp](http://www.cms.hhs.gov/center/coverage.asp).

## **IX. Decision**

CMS has determined that the evidence is adequate to conclude that open and laparoscopic Roux-en-Y gastric bypass (RYGBP), laparoscopic adjustable gastric banding (LAGB), and open and laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS), are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI)  $\geq 35$ , have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity.

CMS has determined that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

A list of approved facilities and their approval dates will be listed and maintained on the CMS Coverage Web site at [www.cms.hhs.gov/center/coverage.asp](http://www.cms.hhs.gov/center/coverage.asp), and will be published in the Federal Register.

The evidence is not adequate to conclude that the following bariatric surgery procedures are reasonable and necessary; therefore, the following are non-covered for all Medicare beneficiaries:

1. open vertical banded gastroplasty;
2. laparoscopic vertical banded gastroplasty;
3. open sleeve gastrectomy;
4. laparoscopic sleeve gastrectomy; and
5. open adjustable gastric banding.

The two non-coverage determinations in the National Coverage Determination Manual (NCDM) remain unchanged - Gastric Balloon (NCDM Section 100.11) and Intestinal Bypass (NCDM Section 100.8).

Modification of the current policy on obesity, found in section 40.5 of the NCDM, will include a reference to the covered surgical procedures and will merge the obesity policy with the final bariatric surgery policy. The modified obesity policy will read as follows (emphasis added to the new language within the policy):

Obesity may be caused by medical conditions such as hypothyroidism, Cushing's disease, and hypothalamic lesions or can aggravate a number of cardiac and respiratory diseases as well as diabetes and hypertension. ***Certain designated surgical services for the treatment of obesity are covered for Medicare beneficiaries who have a BMI  $\geq 35$ , have at least one co-morbidity related to obesity and have been previously unsuccessful with the medical treatment of obesity.***

Treatments for obesity alone remain non-covered.

[Appendices](#) [PDF, 241KB]

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